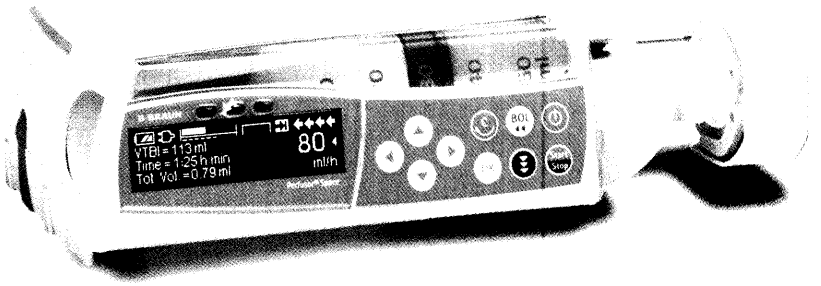
Perfusor® Space
and Accessory

Instructions for Use



Valid for Software 688B

B BRAUN
SHARING EXPERTISE

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SHARING EXPERTISE

PERFUSOR® SPACE OVERVIEW

Arrow up and -down
Scroll through menus, change setting of numbers from 0-9, answer Yes/No questions.
Arrow left and -right
Select data from a scale and switch between digits when numbers are entered. Open a function while pump is running or stopped with the left arrow key.

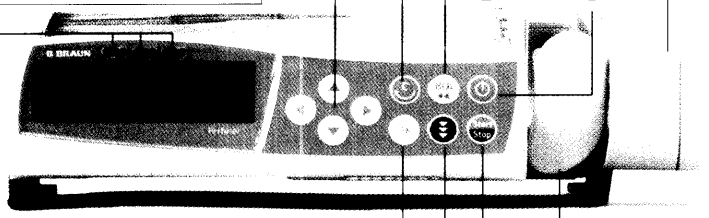
Press to reset single values to zero and switch back to the previous screen/menu level.

Drive head with claws to hold the syringe plunger plate and emergency release button.

Press to initiate bolus.

Press to turn pump on/off.

Yellow LED:	Pre-alarm, reminder alarm
Green / Red LED:	Infusion occuring / device alarm, operating alarm
Blue LED:	Currently connected to SpaceControl



OK

Press to confirm certain values/ settings/alarms.

Press to link the pump to SpaceControl and to assign a barcode after scanning.

Start Stop

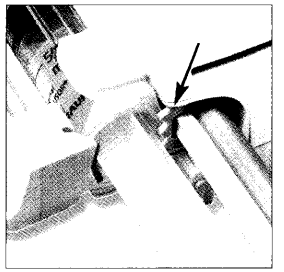
Press to Start/Stop infusion.

Syringe holder locks syringe in position. To remove syringe: Pull and move to the right. Answer question using arrow up key. The drive will automatically move back.

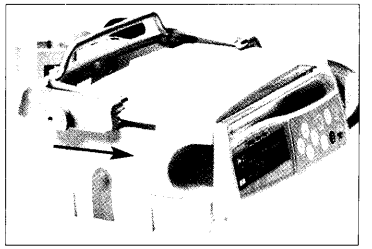
Cover of Battery Compartment
Before changing the battery, always disconnect the pump from the patient and switch off the device.
To remove battery cover push button below the battery compartment and pull cover away from device.
Slide green locking mechanism on back of battery up and take out battery pack for exchange.

Port P3 for SpaceControl

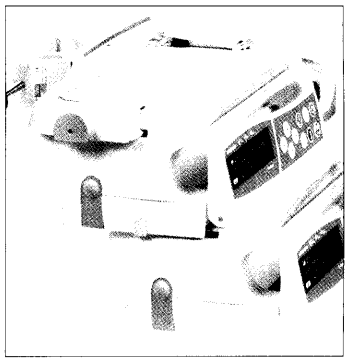
Port P2 for power supply, SpaceStation, connection lead (12V), combi lead and further accessory leads (staff call, service)



Syringe Fixation
Pull and turn the syringe holder to the right to open the green axial fixation (see red arrow). Syringe must be fixed with wings upright in the slot to the left of the axial fixation before closing syringe holder. Make sure that syringe is properly inserted.
Caution: Don't touch piston brake when moving forward.

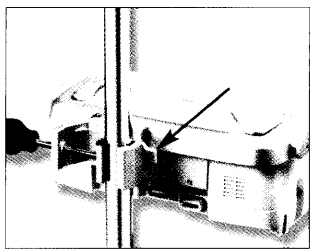


Fixaton of PoleClamp (Universal Clamp)
Line up bar of pump with bar of PoleClamp and slide PoleClamp forward until locking mechanism clicks.
To remove, push handle down and pull PoleClamp backwards.



Transport
A maximum of three pumps (Perfusor® Space or Infusomat® Space) plus one SpaceControl may be stacked together.
Avoid external mechanical influence.

Locking Devices Together
Line up the bar of lower pump with bar of pump above and slide lower pump backwards until the lock clicks and the green buttons are above each other.
To disconnect, push green locking buttons of top pump device and slide bottom pump forward.



Pole Fixation
Push opening of PoleClamp against vertical pole and lock screw tight. Unscrew to release.
For vertical fixation of PoleClamp push lever down and rotate either way until lever clicks into notch. Push lever for rotation.
Caution: Do not lean on pump when attached to pole!

CONTENTS

The Perfusor® Space is according to IEC/EN 60601-1 resp. IEC/EN 60601-2-24 a transportable infusion syringe pump for administrating fluids in nutritional therapy and infusion technique as well as for home care applications. The medical specialist must decide on suitability for application on the basis of the warranted properties and the technical data.

For further details please refer to the Instructions for Use.

PATIENT SAFETY

Read Instructions for Use prior to use. The infusion device should only be used by specially trained staff.

Operation

- The initial training of the Perfusor® Space is to be performed by B. Braun sales personnel or other authorized persons.
- Place Short Instructions Label on top of the pump for quick reference.
- Ensure the unit is properly positioned and secured. Do not position pump unit above patient.
- Prior to administration, visibly inspect the pump and especially the axial fixation for damage, missing parts or contamination and check audible and visible alarms during selftest.
- Connect to patient only after correct syringe insertion and proper fixation of the syringe pressure plate by the claws of the drive head. Interrupt connection during syringe change to prevent incorrect dose delivery.
- Select syringe/catheter suitable for use with the intended medical application.
- Position the infusion line free of kinks.
- Recommended change of disposable each 24 h (or as per national hygiene regulations).
- Installation in medically used rooms must comply with the appropriate regulations (e.g. VDE 0100, VDE 0107 or IEC-publications). Observe national specifications and deviations.
- Do not operate the pump in the presence of flammable anaesthetics to prevent explosion.
- Compare the displayed value with the entered value. Start infusion only if the values are corresponding.
- If staff call is used we recommend checking the equipment once after connecting the pump.
- Protect the device and the power supply against moisture.
- Do not carry the pump device by it's drive mechanism during transportation.
- If the pump device falls or is exposed to force it needs to be examined by the service department.
- The displayed data must always be checked by the user prior to making further medical decisions.
- During mobile use (homecare, patient transport inside and outside the hospital): Make sure the device is securely fixed and positioned. Positioning changes and severe shock can lead to minor changes in the delivery accuracy.

- Avoid applying external force on the drive mechanism during administration.

Other components

- Only use pressure resistant tubes (min. 2 bar/1500 mmHg).
- Where several infusion lines are connected on one single vascular access, the possibility of the lines exerting a mutual influence over each other cannot be excluded.
- Refer to respective manufacturer's information for possible incompatibilities of equipment with respect to drugs.
- Use only compatible combinations of equipment, accessories, working parts and disposables with luer lock connectors.
- The use of incompatible disposables may influence the technical specifications of the device.
- Connected electrical equipment must comply with the relevant IEC/EN-specifications (e.g. IEC/EN 60950 for data-processing equipment). The user/operator is responsible for the system configuration if additional equipment is connected. The international standard IEC/EN 60601-1-1 has to be taken into account.

Safety Standards

Perfusor® Space satisfies all safety standards for medical electrical devices in compliance with IEC/EN 60601-1 and IEC/EN 60601-2-24.

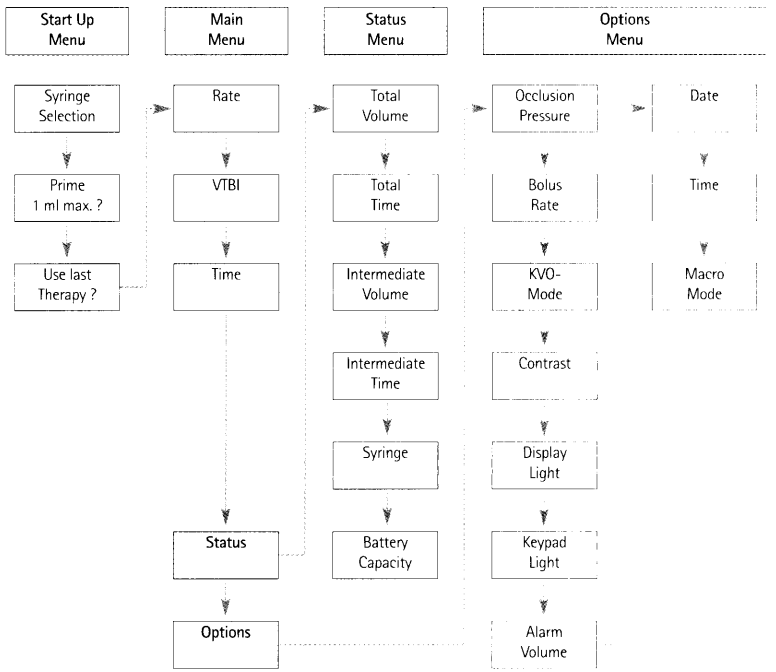
- The EMC-limits (electro-magnetic compatibility) according to IEC/EN 60601-1-2 and IEC/EN 60601-2-24 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones etc.) maintain the recommended protective distances from these devices.

MENU STRUCTURE / OVERVIEW

Cutline

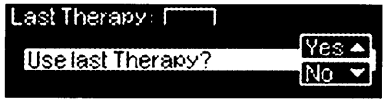
- On/Off button
- Start/Stop button
- Bolus button
- Clear button
- OK button
- Keypad with arrow up, -down, -left, -right button
- Connection button

Menu Structure

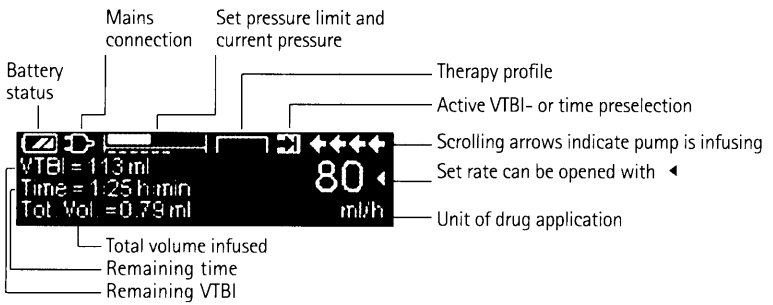


The pump can be customized by (de-)activating the menu itmes of the Start Up- and Options Menu as well as the bolus function via the service program.

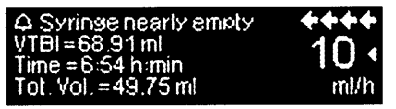
MENU STRUCTURE / NAVIGATION

Display	Meaning
	At the top of the screen the last therapy is indicated. Yes/No question can be answered by pressing ▲ for yes or ▼ for no.
	Parameters which can be changed (e.g. rate in ml/h) are opened with ◄. When editing parameters, switch digits/levels using ◄ ►. White background indicates current digit/level. Use ▲ or ▼ to change current setting. Help text on the bottom/top of the screen indicates options how to proceed (e.g. confirm rate with OK, start infusion with START or clear rate by pressing C).

Typical display during infusion:



	✱ has been pressed while the pump is infusing. Start manual bolus at 1200 ml/h by pressing OK (see top of display) or proceed to set bolus limit with ◄ (see bottom of display).
	This hint pops up if a user tries to edit or change a parameter by pressing ◄ when that parameter is unable to be changed.

Display	Meaning
	Set pressure level with ◄ or ► and confirm by pressing OK. Cancel to edit pressure by using C.
	Pre-alarms are indicated by the message on the display (e.g. "Syringe nearly empty"), an audible tone and a flashing yellow LED. To confirm a pre-alarm press OK.
	In case of an operating alarm (e.g. "Syringe empty") the infusion stops, an audible tone sounds and the red LED is flashing. Confirm alarm by using OK.
	Press and hold ⏻ for 3 sec to turn pump off. A white bar stretches from left to right and counts down the 3 sec.

OPERATION

1.1 Start of Infusion

- Ensure correct installation of the pump device. If the pump is connected to mains, the display states information such as the battery status, the mains connection symbol and the last therapy.
- Press ⏻ to switch on unit. Note the automatic selfcheck: "Selftest active" and the software version are displayed, two audible tones sound and all three LEDs (yellow, green/red and blue) flash once. Information on power supply (battery or mains connection), the set pressure level and the syringe (if syringe already inserted) are displayed. Hence the drive moves backwards.

During the first ever startup of the device, the user is requested to select the language with ⊖ and confirm with ◀. Answer the following question with ▲ in order to take over language before the drive moves backwards.

- Press ⏻ to start with direct entry of therapy parameters or open pump cover and syringe holder to start with syringe insertion.
- Insert syringe with wings of the syringe upright in the slot to the right of the housing. Close syringe holder and pump door. Piston brake moves forward.

Caution: Never leave the pump unattended during syringe loading.

- Confirm syringe type with OK. Type of syringe indicated must coincide with syringe inserted.
- Drive will advance and grip pressure plate of syringe.

Caution: Keep hands away from advancing drive.

Note: Make sure that piston brake moves back into the syringe holder.

- If the prime function is activated, press ▲ to prime infusion set at 1200 ml/h (pressing key once = 1 ml). Interrupt prime function with OK. Repeat procedure until infusion line is fully primed. Then press ▼ to proceed.
- Connect with patient.
- Respectively answer questions in Start Up Menu with ▲ and ▼, until the rate is displayed in the Main Menu.

Enter infusion rate:

- Press ◀ and set rate using ⊕.
- Press Start/Stop to commence infusion. Running arrows on display and green LED above display indicate pump is infusing.

Note: Stop the infusion at any time by pressing Start/Stop. The pump can be turned off at any time by pressing ⏻ for 3 sec.

1.2 Entry With Different Combinations of Rate, VTBI (= Volume To Be Infused) and Time

The Perfusor® Space offers the possibility to enter a volume- and time limit in addition to an infusion rate. When two of these parameters are entered, the third will be calculated by the pump. If a volume and/or time is preselected, an arrow symbol is placed in front of one of these parameters in the Main Menu. It is called the "target". During the infusion of the pump, this target symbol is displayed next to the moving arrows in the run display. This indicates that the pump has been programmed, either with a volume- or time limit. The assignment of the target symbol, apparent in the Main Menu, shows the established parameter for the application (VTBI or time). When the rate is changed, the so-called target parameter is principally not adjusted to the new rate but to the parameter which does not have the target symbol in front. After the infusion has started, the remaining VTBI and time are displayed in the Main Menu and the run display (values are counting down).

1.) Enter VTBI and time: The infusion rate will be calculated and displayed on the bottom of the display.
Target: Volume

- Select VTBI with ⊖ and open with ◀.
- Enter VTBI with ⊕ and confirm with OK.
- Select time with ⊖ and open with ◀.
- Enter time with ⊕ and confirm with OK.

Check calculated rate on plausibility.

Proceed in the same way to calculate 2.) and 3.).

2.) Infusion with volume limit
Enter rate and VTBI: The infusion time will be calculated and displayed on the bottom of the display.
Target: VTBI

3.) Infusion with time limit
Enter rate and time: The infusion volume will be calculated and displayed on the bottom of the display.
Target: Time

Changing already entered values of VTBI and time (rate, VTBI and time already exist at the point of change):

a) Target symbol is placed in front of VTBI:
- Change of VTBI => Adjustment of time. Old and new target: VTBI
- Change of time => Adjustment of rate. Old and new target: VTBI

b) Target symbol is placed in front of time:
- Change of time => Adjustment of VTBI. Old and new target: Time
- Change of VTBI => Adjustment of time. New target: VTBI

Note: Changing VTBI/time is only possible while the pump has been stopped.

1.3 Bolus Application

There are three ways to administer a bolus:

1.) Manual Bolus: Press BOL. Then press and hold button. Fluid is administered as long as button is held down. The infused bolus volume is displayed.

2.) Bolus with volume preselection: Press BOL. Then press ◄ and set bolus limit by using . Press BOL to confirm and start bolus.

3.) Bolus with rate calculation: Press BOL. Then press ◄ and set bolus limit by using . Press to confirm bolus limit. Set time with in which a bolus is to be delivered. Calculated bolus rate is shown on top of the display. Press BOL to confirm and start bolus.

Note: If the bolus limit is not entered after pressing BOL, the pump switches back into the run display automatically.

Caution: Take care not to overdose! Given a bolus rate of 1200 ml/h, 1 ml will be administered in just 3 sec. To cancel bolus infusion at any time press .

1.4 Syringe Change and New Therapy Start

Note: To avoid incorrect dosing, always disconnect the pump from the patient when changing the syringe. Never leave the pump device unattended during syringe change. Before inserting a new syringe check if the axial fixation is properly working.

- Press Start/Stop to stop the infusion. The green LED will disappear. Disconnect the pump from the patient.
- Open syringe holder. Answer question if syringe change should be performed with ▲. Drive unit moves backwards into starting position.
- Open pump door, remove syringe and insert new syringe.

Note: In case the plunger head of the syringe is not released anymore by the claws when performing a syringe change, the emergency release button needs to be pressed to release the claws of the drive head. The emergency release button is placed on the outside of the drive head. It can be released with a pointed pen. Then manually open the claws and take out the syringe.

- Close syringe holder (Note: Piston brake must move forward!) and pump door and confirm inserted syringe type with . Drive advances and grips pressure plate of syringe.

Note: Do not block advancing drive unit with any objects. Piston brake must move backwards into the syringe holder.

- Prime pump if necessary with ▲ then press ▼ to continue.
- Connect the patient to the pump and check set parameters using .

- Press Start/Stop to start infusion.

To start a new therapy after a syringe change:

- Press ⏻ when pump is in the Main Menu.
- Press ▼ and continue to set new therapy parameters with .
- Press Start/Stop to start infusion.

Note: It can be started with a new therapy at any time while the infusion is stopped. Press ⏻ (repeatedly) when the pump is in the Main-, Status- or Options Menu and proceed to follow instructions as described.

1.5 End of Infusion

- Press Start/Stop to stop the infusion. The green LED disappears. Disconnect the pump from the patient.
- Open the syringe holder. Answer question if syringe change should be performed with ▲. The drive moves backwards into the starting position.
- Open pump cover. Remove the syringe, move the syringe holder into an upright position and close the front door.
- Press ⏻ for 3 sec. to switch the pump off. The drive moves into parking position.

1.6 Standby Mode

In the case of extended interruption, the user has the option to maintain the set values.

- Press Start/Stop to stop the infusion. Then press ⏻ for less than 3 sec.
- Confirm the pump is supposed to switch into standby by pressing ▲.
- The default time for standby is displayed. Accept the default time with or change it with (0-24 hours) and then confirm it by pressing .

=> While the pump is in the standby mode, it's display shows the remaining time for this mode. Exit standby by pressing .

ADVANCED OPERATIONS

2.1 Status Request of Pump when Infusion is Running

Press ⏻ to switch between run display and Main Menu while the device is infusing. Navigate through the menu using ⇕ to check parameters. In order to check the menu parameters in the Status-/Options Menu, select "Status" respectively "Options" in the Main Menu, open menu with ◄ and scroll through menu with ⇕.

2.2 Rate Change Without Infusion Interruption and Reset of Status Menu Data

Rate change:

- Press ◄ to open rate when the pump is in the run display.
- Set new value with ✣ and confirm with OK.

Reset Status Menu Data:

The parameters intermediate volume and -time can be resetted when the pump is infusing or when the pump is stopped.

- Select "Status" in Main Menu with ⇕ and press ◄.
- Highlight intermediate volume (in ml) or intermediate time (in h:min) with ⇕ and open parameter with ◄.
- Reset values using ▲.

To reset both total volume and -time, start a new therapy. A second way to reset the parameters when the pump is in the Main Menu: Press ⏻, answer question if the last therapy is to be used with ▲ and reset the values with ▲.

The type of the inserted syringe is displayed in menu item „Syringe" and cannot be changed once it has been confirmed at the beginning of the infusion. The current battery capacity in hours and minutes is displayed in the menu item "Battery Cap.".

OPTIONS

The options functions may be selected and changed while the pump is infusing or stopped. To edit a menu item, select "Options" in the Main Menu and press ◄. Then select desired function with ⇕ and follow the Instructions for Use as described.

3.1 Occlusion Pressure

The higher the pressure level is set at, the higher the pressure level must rise before triggering an occlusion pressure alarm.

- Enter pressure in Options Menu by pressing ◄.
- Choose between nine pressure levels (1=lowest level; 9=highest level) by pressing ◄ or ► and confirm entry with OK.

3.2 Bolus Rate

- Open bolus rate in Options Menu with ◄.
- Change bolus rate with ✣ and confirm setting with OK.

Note: Set bolus rate according to therapy requirements. Take care not to overdose! Given a bolus rate of 1800 ml/h, e.g. 0,5 ml are reached within just one second.

3.3 KVO-Mode

After reaching a preselected VTBI/time, the pump can continue the infusion with a predefined KVO-rate (see "Technical Data"). The duration of the KVO-infusion is set via the service program.

- Open KVO-Mode in Options Menu with ◄.
- Answer Yes/No question with ▲, to activate KVO.

3.4 Contrast / Display Light / Keypad Light

Contrast as well as display- and keypad light can be adjusted individually according to the lighting conditions.

- Open contrast/display light/keypad light in Options Menu by pressing ◄.
- Choose between 9 contrast- and display light levels with ◄ or ► and confirm with OK. For use with light sensitive drugs the keypad- respectively syringe light can be completely turned off.

3.5 Alarm Volume

Chose between 9 different alarm volume levels.

- Open alarm volume in Options Menu with ◄ .
- Set volume with ◄ or ► and confirm entry with OK .

3.6 Date / Time

- Open date/time in Options Menu with ◄ .
- Change date/time with ✣ and confirm with OK .

3.7 Macro Mode

The infusion rate appears larger on the display when the macro mode is activated and the pump is infusing.

- Open macro mode in Options Menu with ◄ .
- Answer Yes/No question by pressing ▲ to activate the macro mode.

For quick activation of macro mode: Press and hold ► while the pump is infusing until the font size changes.

ALARM

The Perfusor® Space is equipped with a audible and optical alarm signal.

Alarm-type	Audible signal	Optical signal			Staff call	User confirmation
		Red LED	Yellow LED	Text		
Device Alarm	yes	flashes	off	device alarm and alarm code (see service program)	yes	Press and hold ⏻ until the pump switches off after a few seconds.
Operating-Alarm	yes	flashes	off	see alarm description	yes	Press OK to acknowledge the audible alarm, alarm text and staff call. The red LED remains on until the infusion is restarted.
Pre-Alarm	yes	off	flashes	see alarm description	(de-)activate via service program	Press OK to mute alarm and turn off staff call. Visible alarm remains until end.
Reminder Alarm	yes	off	flashes	see alarm description	yes	Press OK to mute alarm, turn off staff call and delete the alarm text.
Alarm Hint	yes	off	off	see alarm description	no	Hint disappears without confirmation.

4.1 Pre-Alarms and Operating Alarms

Pre-alarms:
Pre-alarms occur a few minutes (dependable on service settings) prior to operating alarms. During pre-alarms an audible tone sounds, the yellow LED blinks and a staff call is activated (optional). The display message varies depending on the alarm reason. The signal tone and the staff call are turned off with OK . Display and LED stay in pre-alarm until the operating alarm goes off. Pre-alarms don't lead to an interruption of the infusion.

Display message	Pre-alarm reason
"Syringe nearly empty"	Very little fluid is left in syringe.
"VTBI near end"	The preselected volume is nearly infused.
"Time near end"	The preselected time is almost over.
"Battery nearly empty"	The battery is almost discharged.
"KVO active"	Volume/time are reached and the pump continues the infusion at the KVO-rate.

The pre-alarms "VTBI near end" (volume preselection) and "Time near end" (time preselection) can be deactivated via the service program.

Operating alarms:
Operating alarms lead to an interruption of the infusion. An audible tone sounds, the red LED flashes and a staff call is activated. The display states "Alarm" and the reason for the operating alarm. The signal tone and the staff call are turned off with . Corrections are to be made according to the alarm reason.

Display message	Alarm reason
"Syringe empty"	There is no fluid left in the syringe. Due to varying syringe tolerances of syringes from other manufacturers, some fluid may be left inside the syringe. Restarting the infusion leads to a complete depletion of the syringe and shut-off via the pressure sensor. Perform syringe change as described in 1.4.
"VTBI infused "	The preselected volume was infused. Continue therapy or select new therapy.
"Time expired"	The preselected time has ended. Continue therapy or select new therapy.
"Battery empty"	The battery pack is discharged. Connect device with mains and/or exchange battery pack. The battery alarm will be on for 3 min. Then the pump will automatically turn off.
"KVO finished"	KVO is reached. Continue with old or set new therapy.
"Pressure high"	An occlusion occured in the system. The set pressure level was exceeded. A bolus reduction is automatically initiated by the pump. Check if syringe is empty, kinks are in tubing, IV patency and filter patency. Increase occlusion pressure if necessary. Due to varying syringe tolerances of syringes from other manufacturers, a pressure alarm may occur because of high syringe friction forces.
"Syringe not correctly inserted"	The wings of the syringe are not properly inserted. Insertt syringe according to describtion in "Overview Perfusor® Space" as well as 1.1.
"Syringe holder"	The syringe holder was opened during a running infusion. Close syringe holder.
"Battery cover removed"	The battery cover is not properly engaged on the battery compartment. When pushing on the battery cover listen for "click".

"Drive blocked"	An external interference kept the drive unit from advancing. Basically prevent all external interferences. Consider "Patient Safety".
"Claw malfunction"	The emergency release button was pressed and the claws manually opened. Take out syringe and contact technical service department.
"Plunger plate not prop. fixed"	The syringe plunger plate does not attach the plunger plate sensor of the pump. Check system for negative pressure and eliminate cause. Consider "Patient Safety".
"Standby Time expired"	The set standby time has ended. Set new time or continue with previously set therapy.
"No battery inserted"	It is not possible do use the pump without a battery pack. Turn off pump and insert battery pack according to describtion "Overview Perfusor® Space".

The red LED doesn't extinguish until the administration is started again respectively the pump is turned off.

4.2 Reminder Alarms

Reminder alarms only occur in two cases:

1. A syringe is inserted, the pump doesn't administrate, no value is being edited and the device is not operated for two minutes.
   An acoustic tone sounds, the yellow LED blinks and a staff call is activated.
   a) The display states "Reminder alarm!"
   b) The display states "Config. not finished!"
   Confirm alarm with and continue to set therapy/Start Up configuration.
2. A value edition was started but not finished and confirmed. This is also possible with a missing disposable.
   An acoustic tone sounds, the display states "Value not accepted", the yellow LED blinks and a staff call is activated.
   Confirm alarm with and continue to set therapy.

4.3 Alarm Hints

If inproper entries are made the display states corresponding hints (e.g. "Attention! Rate is out of range"; "The parameter can not be modified") and an audible tone sounds. These hints disappear after a few seconds and don't need to be confirmed.

BATTERY OPERATION

The Perfusor® Space is equipped with the latest NiMH-battery. It has an operating lifetime of 8 hours at 25 ml/h when new. For optimal treatment of the battery, the device is equipped with protection against overcharge and deep depletion. The battery pack is charged by the pump during connection to mains. When disconnected from mains or in case of power failure, the pump automatically switches to battery power.

Note: Before changing the battery, always disconnect the pump from the patient and switch off the device.

The battery status indicator is a trend display (low, medium, high). For more detailed information on the current battery capacity (operating time in hours and minutes) please refer to menu item "Batt. Cap." in the Status Menu of the Perfusor® Space.

Important information for battery self-check:
If the battery symbol is blinking during mains operation, the battery is either discharged or has a reduced capacity. In this case, the pump should not be disconnected from mains. If it is necessary to disconnect the pump from mains power for urgent reasons, the user should check to ensure if the battery capacity is sufficient for the proposed use. When the battery symbol blinks permanently (>1h), the battery must be checked by a technician and replaced if necessary.

Directions for optimal battery use:
The actual battery life may vary due to

- ambient temperature
- varying load (e.g. frequent boluses).

The life of a battery can be prolonged if the battery is regularly charged and discharged. For this the pump must be used in the battery mode until the battery alarm sounds. Subsequently, the pump should be connected to mains for at least 6 h. This process is recommended to be done once per month. Furthermore:

- If possible, only charge the battery if it has been completely discharged.
- If a battery, which is not completely discharged, is charged several times, its capacity can be reduced. Its original capacity can be reached again if the battery is completely discharged and then recharged.
- Under normal temperature conditions a battery can be charged and discharged approx. 500 times before its lifetime decreases.
- When the pump is not connected to mains power the battery discharges itself slowly. This can occur even when the pump is not operating. The original capacity will only be reached after several cycles of charging and discharging.
- The battery operating time only can be realized if the pump operates continuously with a fully charged battery at room temperature. The display of the battery operating time on the pump is an approximate value based on the current delivery rate. If the battery is aged it may differ from the actual achievable operating time.

Caution: Batteries may explode or leak if they are opened or incinerated. Consider disposal directions!

COMPATIBLE SYRINGES

The syringe types listed in the following tables can be used with the Perfusor® Space. Please refer to the listed material number (Mat. No.[1]) to ensure specific syringe brand compatibility.

The Time to Occlusion[2] alarm has been measured at 5ml/h. The measured data are typical average values which can vary because of possible syringe tolerances.

Manufacturer:
B. Braun

Syringe Type B. Braun	Omnifix 2 ml	Omnifix 5 ml	Omnifix 10 ml	Omnifix 20 ml	Omnifix 30 ml	Omnifix 50 ml
Mat. No.[1]	461 7029	461 7053	461 7100	461 7207	461 7304	461 7509
Time to Occl.[2]	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:39	0:58	0:47	1:04	1:13	1:16
P 9 [mm:ss]	1:05	1:32	2:08	3:26	6:07	13:46

Syringe Type B. Braun	OPS 20 ml	OPS 50 ml
Mat. No.[1]	872 8615	872 8810
Time to Occl.[2]	typ.	typ.
P 1 [mm:ss]	1:08	1:34
P 9 [mm:ss]	4:35	15:27

Manufacturer:
TYCO EU

Syringe Type TYCO EU	Monoject 3 ml	Monoject 6 ml	Monoject 12 ml	Monoject 20 ml	Monoject 35 ml	Monoject 50/60 ml
Mat. No.[1]	1100-603495	1100-606159	1100-612173	1100-620036	1100-635430	1100-650090
Time to Occl.[2]	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:51	0:56	1:04	1:19	1:32	2:23
P 9 [mm:ss]	1:16	1:41	3:27	5:27	12:05	15:58

Manufacturer:
TYCO USA

Syringe Type	Monoject	Monoject	Monoject	Monoject	Monoject	Monoject
TYCO USA	3 ml	6 ml	12 ml	20 ml	35 ml	50/60 ml
Mat. No.[1]	8881-513934	8881-516937	8881-512878	8881-520657	8881-535762	8881-560125
	8881-713005	8881-716008	8881-712023			8881-760089
Time to Occl.[2]	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:41	0:50	1:07	1:13	1:27	1:35
P 9 [mm:ss]	1:17	2:07	3:45	4:49	11:50	15:46

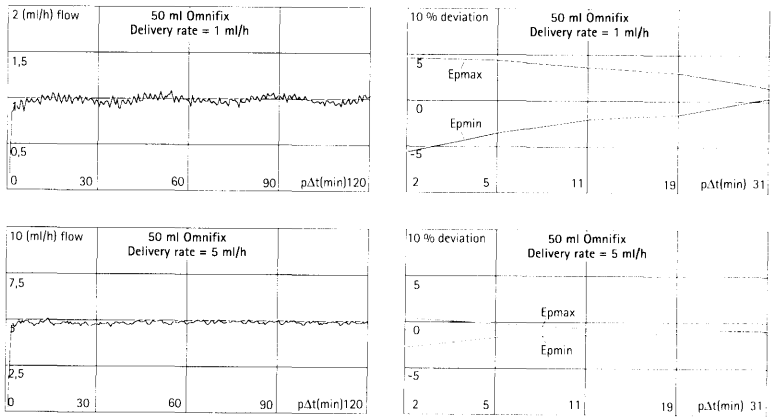
Manufacturer:
Becton
Dickinson

Syringe Type	Plastipak	Plastipak	Plastipak	Plastipak	Plastipak	Plastipak
B-D EU/USA	3 ml	5 ml	10 ml	20 ml	30 ml	50/60 ml
Mat. No.[1]	309585	309603	309604	309661	309662	309663
	300910	300911	300912	300913	300863	300865
				300134		300869
				300629		
Time to Occl.[2]	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:53	0:55	1:15	2:05	2:14	2:53
P 9 [mm:ss]	1:15	1:34	3:27	6:30	6:36	15:34

Manufacturer:
TERUMO

Syringe Type	3 ml	5 ml	10 ml	20 ml	30 ml	50 ml	60 ml
TERUMO EU/USA/JAP							
Mat. No.[1]	3SS*03L	3SS*05L 1SS*05LZ1	3SS*10L 1SS*10LZ1	3SS*20L SS*20ES	1SS*30LZ1	2BS-50LG	3SS*60L
Time to Occl.[2]	typ.	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:43	0:35	0:55	2:12	2:25	3:01	3:34
P 9 [mm:ss]	1:17	1:16	4:48	7:53	8:18	16:55	17:03

START UP GRAPHS AND TRUMPET CURVES



The graphs show the accuracy/uniformity of flow in relation to time. They allow for the following:
The delivery behaviour or delivery precision is essentially influenced by the type of (disposable syringe) used. If other syringes (disposables) than those stated in the order data are used, deviations from the technical data of the pump cannot be excluded.

Trumpet Curves
Measured values for second and last hour in each case.
Measurement interval $\Delta t = 0.5$ min
Observation interval $p \times \Delta t$ [min]

Start-up Curves
Measurement interval $\Delta t = 0.5$ min
Measurement duration $T = 120$ min
Flow Q_i (ml/h)

TECHNICAL DATA

Type of unit	Infusion Syringe Pump
Classification (acc. to IEC/EN 60601-1)	Defibrillator-proof; CF equipment Protective Class II
Class (acc. to Directive 93/42 EEC)	IIb
Moisture protection	IP 22 (drip protected for horizontal usage)
External power supply:	
• Rated voltage	Via B. Braun SpaceStation or optional mains adaptor (rated voltage 100 ... 240 V AC~, 50/60 Hz) for stand alone operation
• Power input	11 ... 16 V DC ⎓ via external power supply 12 V or via SpaceStation
Staff call	Max. 24 V / 0,5 A / 24 VA (VDE 0834)
EMC	IEC/EN 60601-1-2 / 60601-2-24
Time of operation	100 % (continuous operation)
Operating conditions:	
• Relative humidity	30 % ... 90 % (without condensation)
• Temperature	+5 ... +40 °C
• Atmospheric pressure	500 ... 1060 mbar
Storage conditions:	
• Relative humidity	30 % ... 90 % (without condensation)
• Temperature	-20 ... +55 °C
• Atmospheric pressure	500 ... 1060 mbar
Type of battery pack (rechargeable)	NiMH
Operating time of rechargeable battery	Approx. 8 hours at 25 ml/h
Recharging time	Approx. 6 hours
Weight	Approx. 1.4 kg
Dimensions (W x H x D)	249 x 68 x 152 mm
Volume preselection	0.1 - 99.99 ml in increments of 0.01 ml 100.0 - 999.0 ml in increments 0.1 ml 1000 - 9999 ml in increments 1 ml
Time preselection	00:01 - 99:59 h
Accuracy of set delivery rate	± 2 % according to IEC/EN 60601-2-24
Occlusion alarm pressure	9 levels (0.1-1.2 bar in increments of approx. 0.1375 bar)
Alarm in the case of incorrect dosage	For incorrect dosages of 0.1 ml due to malfunctions of the device the pump will automatically shut off
Technical inspection (safety check)	Every 2 years

Selectable delivery rates	Continuous infusion rate range / bolus rates in dependence on syringe sizes:

Syringe sizes	Cont. rates*	Bolus rates
[ml]	[ml/h]	[ml/h]
[illegible]	0.01 - 200	1 - 1800
	optional	
	0.01 - 999.9	
[illegible]	0.01 -100	1 - 1200
[illegible]	0.01 -100	1 - 800
[illegible]	0.01 -50	1- 500
[illegible]	0.01 -50	1 - 300
[illegible]	0.01 -25	1 - 150

Rate increments	0.01* - 99.99 ml/h in increments of 0.01 ml/h 100.0 - 999.9 ml/h in increments of 0.1 ml/h
Accuracy of bolus infusion	typ. ± 2 %
Max. bolus after bolus reduction	≤ 0.2 ml
KVO-rate	rate ≥ 10 ml/h: KVO-rate 3 ml/h rate < 10 ml/h: KVO-rate 1 ml/h rate < 1 ml/h: KVO-rate = set rate
Computer connection	USB connection in combination with B. Braun interface lead CAN SP (8713230) including electrical insulation. Please pay attention to safety notices.

*as default, infusion rates starting from 0.1 ml/h can be set

WARRANTY / TSC* / SERVICE / CLEANING

Responsibility of the Manufacturer

The manufacturer, assembler, installer or importer is responsible for the effects on safety, reliability and performance of the equipment only if:

- assembly operations, extensions, re-adjustments, modifications or repairs are carried out by authorized personnel,
- the electrical installation of the relevant room complies with the appropriate requirements (e.g. VDE 0100, 0107 and/or the IEC-publications resp. national requirements),
- the equipment is used in accordance with the Instructions for Use and
- the Technical Safety Checks are carried out regularly.

Warranty

The CE mark confirms that this medical product complies with the "Council Directive on Medical Devices 93/42/EEC" dated 14th June 1993.

B. Braun Melsungen AG

B. Braun provides 24 months warranty, as from the date of delivery, for every Perfusor® Space (12 months for every Battery Pack SP). This covers repair or replacement of parts damaged as a result of design/manufacturing errors or material defects. Modifications or repairs to the unit undertaken by the user/operator or by third parties invalidate the warranty.

The warranty does not cover the following:
Elimination of faults attributable to incorrect/unauthorized handling, or to normal wear and tear.
Defective rechargeable battery packs can be returned to B. Braun for further disposal.

Technical Safety Check*) / Service

The Technical Safety Check is recommended to be carried out every 2 years and should be documented. Servicing work must be carried out exclusively by B. Braun trained personnel.

Check regularly

Check for cleanliness, completeness and damage. Use only according to Instructions for Use. Check the following items each time the pump is switched on: self-check, audible alarm, process- and alarm control indication.

Cleaning

Clean external surface of pump using mild soap suds. Do not use spray disinfectants at the mains power connection. Recommended: disinfectant for wiping available from B. Braun (e.g. Meliseptol®). After cleaning, allow the device to vent for at least 1 min prior to use. Do not spray into openings in the device. Be sure to observe the instructions provided concerning waste disposal and hygiene for batteries and disposables. Wipe magnifying- and displayglas on front of pump door only with a soft cloth.

Inspection on Delivery

Despite careful packaging, the risk of damage during transport cannot be entirely prevented. Upon delivery, please check that all items are present. Do not use a damaged device. Contact the service department.

Items included

Perfusor® Space, rechargeable battery pack, Instructions for Use-Set.

INSTRUCTIONS FOR USE ACCESSORY

PoleClamp SP (8713130)

A maximum of three B. Braun Space pumps and one SpaceControl can be stacked together when used with the PoleClamp SP. For detailed instructions on secure fixation of the PoleClamp SP please refer to "Overview Perfusor® Space" and "Patient Safety".

Power Supply SP (8713110-8713114)

The Power Supply SP is adequate to supply power for a single pump and one SpaceControl.

1.) Connect plug of Power Supply SP with socket P2 on back of pump (ensure that plug "clicks").

2.) Push power plug into wall outlet.

Note: For disconnection from pump, press lever on plug down.
A maximum of three plugs can be stacked upon each other in socket P2.

Technical Data: 100 – 240V AC~, 50/60 Hz

Combi Lead SP 12 V (8713133)

The Combi Lead SP can connect up to three pumps. All pumps can then be operated via the Connection Lead SP (12 V).

1.) Connect plug of the Combi Lead SP 12 V with the socket P2 on the back of the pump.

2.) Connect plug of Connection Lead SP with Combi Lead SP.

3.) Push plug of Connection Lead SP into 12 V connector.

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Battery-Pack SP (8713180)

For further information on the Battery-Pack SP (NiMH) see "Battery Operation".

PCA-Button SP (8713190)

For detailed information on PCA therapy and installation of the PCA-Button SP, please refer to the Instructions for Use manual of the B. Braun SpaceControl.

Interface Lead CAN SP (8713230)

Interface Lead CAN SP is needed in order to set up a connection between the SpaceStation/pump and the computer outlet (for service requirements).

1.) Push plug into socket F3 on the SpaceStation or P2 on the pump and connect with the CAN/USB converter.

2.) Connect CAN/USB converter to computer outlet as described in the Instructions for Use manual.

Caution: The Interface Lead CAN SP is only to be used by the service department; never use while patient is connected.

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Connection Lead SP (12 V) (8713231)

Install the Connection Lead SP (12 V) in the following way:

1.) Connect plug to socket P2 on back of pump or F3 on SpaceStation respectively.

2.) Put the connection lead into the car socket.

3.) If necessary, remove red adaptor of motor vehicle connector by slightly turning and simultanously pulling.

The green LED of the electronic box shows the operating voltage. The mains connector can easily be replaced by another plug if required.

Caution: Do not connect the pump to a patient during external car battery charging!

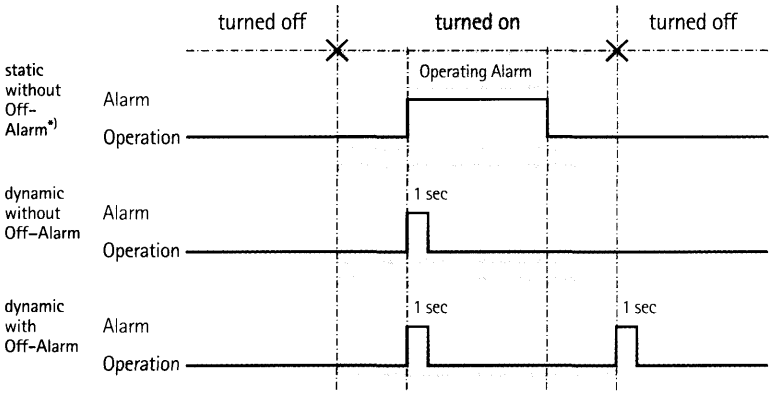
Note: A maximum of three plugs can be stacked upon each other in socket P2.

Connection Lead for Staff Call SP (8713232)

To connect the Perfusor® Space to staff call, use the Connection Lead for Staff Call SP. The staff call needs to comply with the requirements of VDE 0834 (consider country specific regulations).

Note: Test staff call signalling before every use.

The Perfusor® Space offers three different staff call operating modes. They are displayed in the signalling scheme. Consider the staff call of the hospital when choosing an operating mode. Choose the operating mode via the service program.



*) in the mode static without Off-Alarm, the staff call can be surpressed with ○×

Caution: The user should always closely observe the local pump alarms as well.

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Technical Data

	Connecting Wire	
	white and green	white and brown
Alarm	disconnected	connected
Operation	connected	disconnected

Polarity of connexion is arbitrary:
max. 24 V / 0.5 A / 12 VA

	Art. No.
B. Braun Perfusor® Space (100 – 240 V)	871 3030

Recommended accessories for the B. Braun Perfusor® Space:

PoleClamp SP	871 3130
Power Supply SP (Euro Plug)	871 3110
Power Supply SP (UK Plug)	871 3111
Power Supply SP (US Plug)	871 3112
Power Supply SP (Australian Plug)	871 3113
Power Supply SP (Universal Plug)	871 3114
Combi Lead SP 12 V	871 3133
Battery Pack SP (NiMH)	871 3180
PCA-Button SP	871 3190
Interface Lead CAN SP	871 3230
Connection Lead SP (12 V)	871 3231
Connection Lead for Staff Call SP	871 3232

Original Perfusor® Syringes

Original Perfusor® Syringe 50 ml without needle	872 8844F
Original Perfusor® Syringe 50 ml with aspiration needle	872 8810F
Original Perfusor® Syringe 50 ml with aspiration needle and particle filter	872 8852F
Original Perfusor® Syringe 50 ml black with aspiration needle and particle filter	872 8828F
Original Perfusor® Syringe 20 ml without needle	872 8615
Original Perfusor® Syringe 20 ml with aspiration needle	872 8623
Omnifix® 50/60 ml Luer Lock	461 7509F
Omnifix® 30 ml Luer Lock	461 7304F
Omnifix® 20 ml Luer Lock	461 7207V
Omnifix® 10 ml Luer Lock	461 7100V
Omnifix® 5 ml Luer Lock	461 7053V
Omnifix® 2 ml Luer Lock	461 7029V

Original Perfusor® Lines

Original Perfusor® Line, made of PVC; 50 cm 825 5172
Original Perfusor® Line, made of PVC; 150 cm 872 2960
Original Perfusor® Line, made of PVC; 200 cm 872 2862
Original Perfusor® Line, made of PVC; 250 cm 825 5490
Original Perfusor® Line, made of PVC; 300 cm 825 5253
Original Perfusor® Line, made of PE; 50 cm 825 5059
Original Perfusor® Line, made of PE; 100 cm 825 5067
Original Perfusor® Line, made of PE; 150 cm 872 2935
Original Perfusor® Line, made of PE; 200 cm 872 3060
Original Perfusor® Line, made of PE; 250 cm 827 2565
Original Perfusor® Line, type Safesite, made of PVC,
with Safesite safety connector; 150 cm 872 2820
Original Perfusor® Line, type Filter, made of PVC,
with injection filter 0.22 µm; 200 cm 872 3001
Original Perfusor® Line, type PCA, made of PVC
with back check valve; 168 cm 872 6019
Original Perfusor® Line, type MR, made of PVC,
with swivel nut; 75 cm 872 2870
Original Perfusor® Line, type MR, made of PVC,
with swivel nut; 150 cm 825 5504
Original Perfusor® Line, made of PE, black; 150 cm 872 3010

Technical Safety Check (TSC)

Index a
(Master - to be added to the documentation)

Checklist for Technical Safety Check – Every 24 Months

Device: Perfusor® Space
Manufacturer: B. Braun Melsungen AG

User

Observe the Service Manual and the instructions for use. All measured values are to be documented. Accessories used should be included in testing. Make exclusive use of calibrated measuring instruments.

Article No.	Unit No.	Year of Procurement

Visual Inspection	Electrical Safety In accordance with IEC / EN 60601-01 or VDE 0750 and VDE 0751.	Functional Inspection
❒ Perfusor® Space: Cleanliness, completeness, damages and safety affecting defects, damages and readability of the labels, syringe holder with blade, syringe positioner, diaphragm in the drive head, axial clearance of the drive, screw covers, connectors "P2" and "P3" ❒ Accessories: Cleanliness, completeness, damages and safety affecting defects, damages and readability of the labels ❒ Check the unit and the accessories for compatibility	The patient and housing leakage current of the Perfusor® Space is caused exclusively by the operating voltage supply (Plug-In Power Supply SP or SpaceStation). The Technical Safety Checks of the Plug-In Power Supply SP (drawing No. M001 32 10 05 F04) or of the SpaceStation (drawing No. M690 00 00 46 F04) serve to check whether both limit values are met.	❒ Locking with second unit ❒ Magnets of the operating unit ❒ Battery compartment cover and function of magnet Switch on unit with power supply ❒ Selftest ❒ Audible alarm ❒ Visual alarm ❒ Staff call ❒ Indicator lamps (LEDs) ❒ Status display ❒ Illumination of syringe compartment ❒ Syringe recognition of all selectable syringe types and syringe sizes ❒ Functional inspection according to the instructions for use and dependent on the configuration Switch on unit without power supply ❒ Selftest Alarms ❒ Push-button sensor ❒ Syringe size ❒ PCA locking ❒ Syringe holder – blade force ❒ Syringe positioner

(Part 1 of 2)

Technical Safety Check (TSC)

Index a
(Master - to be added to the documentation)

Visual Inspection	Electrical Safety In accordance with IEC / EN 60601-01 or VDE 0750 and VDE 0751.	Functional Inspection
		Pressure cut-off (with syringe gauge, Art.-No.: 0770 3368) Settings on the unit: syringe type: "#gauge OPS50" **WARNING** REMOVE SYRINGE GAUGE ONLY WHEN RELEASED. DANGER OF INJURY! Strain gauge (DMS) pressure measurement ❒ Pressure stage 1 8 ... 13 N ❒ Pressure stage 3 24 ... 30 N ❒ Pressure stage 8 65 ... 73 N Motor power limitation (convert syringe gauge) ❒ Pressure stage 1 12 ... 23 N ❒ Pressure stage 3 32 ... 44 N ❒ Pressure stage 6 61 ... 75 N

(Part 2 of 2)

Mechanical Aids and Measuring Instruments Used	Accessories Used	
❒ Syringe gauge, serial No. _____ Calibrated on _____ ❒ Service plug	❒ Plug-In Power Supply SP _____ ❒ Battery module _____ ❒ Staff call lead _____ ❒ _____	

Test result:

Defects found which could endanger patients, users or third parties: Yes No

Measures to be taken: Repair

_____

Special features / documentation:

Inspection performed by:
Unit handed over on:
To:
Date / Signature:
Next deadline for TSC: